TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
(NATIONAL COTTON COUNCIL)
OF AMERICA))

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IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:	)
	)
STAKEHOLDERS MEETINGS	)
(NATIONAL COTTON COUNCIL	)
OF AMERICA	)

Training Rooms 1 and 2
4700 River Road
Riverdale, Maryland

Monday,
February 23,2004

The parties met, pursuant to the notice, at 1:37 p.m.

BEFORE: CINDY SMITH, Deputy Administrator
Biotechnology Regulatory Services

ATTENDEES:

For USDA, Animal Plant Health Inspection Service (APHIS) and Biotechnology Regulatory Services (BRS):

REBECCA BECH
JOHN TURNER
SUSAN KOEHLER
NEIL HOFFMAN

For National Cotton Council of America:

GARRET VAN DUYN

Participant:

ROBYN ROSE

P R O C E E D I N G S

(1:37 p.m.)

MS. SMITH: I will start with some opening remarks and then we will turn it over to you. Then we are going to have some more people joining us. We've got a couple things going on upstairs; as always, trying to do a couple things at once.

MR. VAN DUYN: That's the way you get things done.

MS. SMITH: That's right. Welcome to our stakeholder discussion series on our upcoming environmental impact statement, or EIS, and revised Biotech regulations. We essentially have two purposes for today's meeting. The first is to share information on our plans to proceed for our EIS, as well as our new regulations. The second is to gather diverse and formative input which will support thoughtful and effective decisionmaking on our part in the development of our new revised plant biotechnology regulations.

We want to thank you for taking the time from your busy schedules to participate in this meeting and to share your thoughts with us. As you likely know, we participated in some interagency discussions with EPA, FDA and the White House and

concluded them recently. At the conclusion of those meetings, there was agreement that we would update our regulations based on the authorities and the Plant Protection Act of 2000.

While we concluded that we have a very effective regulatory system in place, we also saw an opportunity to factor in the experience that we have gained over our years of regulating and looking at the authorities in the Plant Protection Act to enhance our regulations and particularly position ourselves better for technologies in the future, such as the eventual commercialization of pharmaceutical and industrial field testing, the commercialization of products from field testing of those plants.

While there was general agreement at the conclusion of those interagency discussions about generally having procedures in terms of the logging in our regulatory framework, there's a lot still to be flushed out, which these kinds of stakeholder sessions, as well as the public-input process, will position us well to fully flush out our regulations in a way that will best be able to address a number of issues raised by a variety of stakeholders.

What we would like to do in this meeting today is just hear your thoughts, as well as open it

up for a give and take of ideas. If you'd like to have kind of more of a collaborative discussion, we're open to that as well. We have a unique opportunity to have this kind of a give-and-take discussion at this point in the process since we have not entered into formal rulemaking as yet.

Our discussion will be professionally transcribed, however, by the transcriber at the head of the table. First, we want to do that so that we have an accurate record our discussions, so that we have that information captured in a way that we can refer back to your input as we go forward in the process. Secondly, in the interest of transparency and fairness to all the rest of the stakeholders, we want each stakeholder group, or a member of the public, to have the benefit of the discussion that we have with every other group that comes in.

Some groups have additional expertise than others or expertise in certain areas that other stakeholders would benefit from hearing what the dialogue was. In addition to professionally transcribing the proceedings, we have the capability of capturing information on the flip chart. If there's something that you want to diagram for us or some thoughts you'd like us to capture to build on in

terms of discussion, we have that capability as well.

Of course, I should emphasize that while we have been sharing information today in terms of our thinking in Biotechnology Regulatory Services, I should also acknowledge that we're at the beginning of a significant process where we will take public and stakeholder input very seriously. So I'm thinking it's likely to evolve somewhat significantly as we go through this public process.

In addition, other officials at USDA, such as the APHIS administrator, the undersecretary, the secretary, our general counsel, will all most certainly have insightful guidance for us as we go through the process. So while we may talk about a number of different areas in our thinking today, all of that really is very much up for reworking and rethinking as we go through the months ahead, as this will likely be quite an evolving process.

Since it will be hard to predict what our final regulations will look like, what I would like to do is briefly share with your our overall BRS priority areas of emphasis. These are five areas of emphasis that we use to guide our regulatory and policy decisionmaking and operations. By keeping these areas of emphasis in mind, it should give you some insight

into some of the assumptions and the background thinking of what we will be going through.

The first area is rigorous regulation. Rigorous regulation was thoroughly and appropriately evaluates and ensures safety and is supported by strong compliance and enforcement. The second is transparency. Transparency of the regulatory process and regulatory decisionmaking to stakeholders and the public, we believe is critical to public confidence, and we believe public confidence is a very important component of an effective regulatory system.

A science-based system ensuring that the best science is used to support regulatory decisionmaking to assure safety, we also believe is critical to an effective system. The fourth area is communication, coordination and collaboration, with a full range of stakeholders. The final area is international leadership, ensuring that; international biotechnology standards are science-based; that we support international regulatory capacity building; and that we consider international implications of policy and regulatory decisions.

With that brief fact on information, I would like to open up the floor for your comments and discussion. I will ask you to start by stating your

name and your organization and just a little bit about your organization for the purpose of the public record. As we have questions, we will ask questions here at the table. At the table, you have members of the BRS management team, and then you have our colleagues who are on the staff and other parts of APHIS.

As our colleagues have questions, they will write them down and submit them up, just to help us kind of manage the flow of the questions. Then when anyone from the back has their question read, we are going to ask you to come up to the microphone so that we can make sure that we have you heard and for the public record as well.

So with that, I will thank you for coming and open it up for your questions or comments.

MS. VAN DUYN: Thank you. My name is Garret Van Duyn with the National Cotton Council. I am the manager of the environmental and biotechnology policy for the Council. The National Cotton Council is the trade organization for the United States cotton industry, representing the producers, the generous cooperative warehousemen, oil seed crushers, manufacturers and merchants for the cotton industry. We cover all aspects of the cotton industry, and our

major constituents are the producers.

While I don't have any formal prepared statement, I would like to say that the Cotton Council has gone on record many times in many publications in support of the USDA, EPA and FDA's regulatory system and favors a strong regulatory approach to biotechnology. In addition, we believe that the current regulatory system has been very fair and efficient and good for the cotton industry and we would like to thank the regulatory agencies for their work on this area.

We agree with the priority areas that you just described, especially areas such as a science-based system and international leadership for biotechnology, since it is a developing technology. With that, I will just move straight on to the environmental impact statement that has been released on the Federal Register and ask some questions that I have regarding the 11 questions that were mentioned by APHIS.

Beginning with the first consideration, which states: including genetically engineered plants that may pose a noxious-weed risk and genetically engineered organisms that may be used as biologic control agents and if regulatory requirements for

these organisms need to be established.

I was interested in knowing what technologies or what examples that you were thinking of when you had this in mind. Are you thinking about the potential for -- using cotton as an example -- fungal resistant varieties of cotton, which are developed through genetic engineering; or are you referring to something like the alphatoxin, which was developed to reduce alphatoxin in Arizona?

MS. SMITH: I will answer generally in terms of what we're thinking about with the authority and then invite John Turner, who is our policy coordination producer and director. It's John's responsibility to oversee development of our new regulations. Generally, what we are looking at in terms of these other two authorities, we didn't have specific process traits in mind. But, generally, what these authorities allow us to do is to look more broadly at the issues that may be raised by genetically engineered plant varieties.

Historically, what we have had the ability to look at or the authority to look at is just the plant health risk that might be posed. Expanding, for example, to the noxious-weed authority will allow us to do is to also consider public health, environmental

safety, and a variety of other factors that are relevant to the definition of a noxious weed.

What we will be doing is we will be looking at those broader areas as we evaluate whether certain things should be maintained under regulation or what kinds of regulatory decisions should be made in conjunction with either the field-testing movement or the release of that kind of an organism.

Did you want to add anything, John, in terms of specifics?

MR. TURNER: I think that covers it very well. The genetically engineered cotton products, you know the ones that have come through. I think the ones that you mentioned would be regulated under our current system and would be regulated under the future system. The different authority gives us more flexibility in the way that we regulate.

MR. VAN DUYN: Would you envision that this would apply mostly to the pharmaceutical or industrial compound containing plants, or would it apply to other novel technologies that are on the infancy of the procedure?

MS. SMITH: Well, it would apply to most genetically engineered plants. What it would allow us to do is to look at additional areas. So for

pharmaceuticals and industrials, for example, that are not intended to be in the true food and feed supply with the new authorities, we can evaluate the food safety. Where we don't have that ability now, we can factor the results of that food-safety valuation into all kinds of requirements to be placed on the field testing of that trait in that crop.

MR. VAN DUYN: If it does, does that possibly conflict with FDA's responsibilities in the regulation of biotechnology?

MS. SMITH: That's a good question. One of the things we talked about to quite an extent in the interagency process is: How, in any updating of our regs, we don't want to duplicate FDA's efforts but we want to complement them. One of the goals that we have agreed and that FDA has agreed in terms of looking at any changes to our regulations is: the complementarity of our systems.

So, for example, how we might see that play out is when we're looking at what the field testing requirements should be for a pharmaceutical and an industrial crop, for example, in our food-safety evaluation, we would look at whether FDA has already done one. Certainly, it's not our intention to repeat or duplicate any effort done by FDA. So wherever

there's a situation, which another agency has the ability to provide some of the information that would factor into our authority, we would take that information from that agency. If it's already been addressed adequately by another agency, they wouldn't repeat that, but we would factor that into our decision.

MR. VAN DUYN: So it would probably be more accurate to state that you would be attempting to gather information, whether by obtaining existing information such as a data call-in like the EPA uses, or requiring additional studies or doing additional studies on the plants themselves?

MS. SMITH: That's correct.

MR. VAN DUYN: Okay. All right. Then moving on to the second question that you posed: APHIS is considering revisions to the regulations that would define the specific risk-based categories for field testing; and then you have three tiers that you put down here. One would be low risk. Two would be noxious weed, and three would be pharmaceutical- or industrial-containing compounds.

In the first tier, or the low-risk tier, I was interested in knowing what kind of criteria that you had in mind to determine what fits into that

category. It is our thought that the current technologies that are out there, defined as non-novel technologies. It's a crystalline BT protein -- would be not as novel as a pharmaceutical compound; and thereby, you've seen the product in the field in a couple of different crops and so forth.

Now, of course, the particular risk of this crop would depend on what the crop is. You have corn, which is not as self pollinating as, say, cotton or soybeans. So the risk on cotton or soybeans would be much lower as far as gene flow or gene spread is concerned. However, if it's been proven that the crystalline protein, the BT proteins, have no human health or environmental health risks, then you can deregulate a plant and feel good about that.

Where I am going with this is: When you make a determination that something is a low risk, are you planning on putting in place any sort of data considerations for future products? For instance, let's say Company A proposes to release a new type of BT protein. After going through the review and after developing all the data, the third or fourth or fifth copycat product, let's say, is deemed to be a low risk and doesn't need that kind of evaluation.

Are you planning on putting any sort of data

compensation rules or any way in which you are not creating a competitive dichotomy between the person that goes out and initiates the development of the product and puts the money into the R&D, versus the person that just comes up behind them and takes advantage of that without putting forth any sort of compensation?

MS. SMITH: First, to go back to your initial point about the material for the categories, I would say we are talking about making the categories move from a lower risk to a higher risk, based on a variety of factors. You mentioned some of the things that we're looking at, but I'd emphasize that we're very open and are looking forward to hearing all of the suggestions that come in through this process in terms of criteria.

Then your second point, one of the things that we are trying to build into the system is to look where there is a significant amount of familiarity and reduce the regulatory burden there, where it's appropriate. If there's enough familiarity and safety information that suggests that something doesn't need the same level of regulation that it has needed in the past, then that's one of the things that we want to consider in the new system.

There may be some things that we've seen enough times, and there's enough data and experience that there may not yet need the same level of scrutiny within the multitiered risk-based permitting system that we are proposing that some other product that would need if it didn't have the same kind of experience.

Anything else, John, you want to add in terms of this?

MR. TURNER: No. I think that's summarizes it, what we're looking at and whether it's appropriate to lighten the regulatory burden? I'm curious about your question, whether this is a major industry concern that this business of data compensation so that the one company produces the original data package --

MR. VAN DUYN: In the world of pesticides, under FIFRA, a person who registers a pesticide as patent protection on their product between 10 and 13 years, depending on the number of mono-crop uses they have -- once the patent expires and other companies can begin using that type of product or active ingredient, then those companies can come in and then cite the data that the original company used in their registration. However, under FIFRA, that company

needs to compensate the original company, the developing company, for the use of that data.

Now over time, this data loses its value as more general information becomes known about the technology. But immediately following the registration of the technology and for some time period afterwards, it's usually developed by some sort of arbitrary process -- there can be several tens of millions of dollars tied up in data compensation. So it could be something very significant.

It takes tens of millions, if not hundreds of millions of dollars, to bring a product from development all the way into the field for commercialization. A significant portion of that is the development of data, human-tox studies, animal-tox studies, environmental degradation, things of that nature which probably would not apply in most situations.

But Biotech has its own different set of scientific needs. So gene flow would be something that would not be shared with pesticides but would be unique to Biotech, and those could be rather expensive. If you start talking about secondary effects and if you start getting endangered-species effects, or what have you, there are all those avenues

that can be taken, and all of those are going to require someone to go out and contract somebody or to do some sort of research and all that costs money to do.

MS. KOEHLER: Can I ask a clarifying question?

MS. SMITH: Yes.

MS. KOEHLER: Are you suggesting, then, say for the purposes of commercialization, if someone would be submitting a petition for deregulation for something that is similar to something that's already been deregulated, are you suggesting that if it is reduced, the -- requirements for those or somehow allow for the previous person to be compensated?

MR. VAN DUYN: It would be our suggestion that you speak with the registrants and the people who are going to end up paying the bill for that. We can't speak for the registrants. They may think it's perfectly acceptable. If that's the case, then it's their business and it's their business decisions. So that's fine, but consideration needs to be given so that there isn't some sort of competitive advantage given to one company over another with a like product.

So we're not in a position to speak for them, but they should be consulted on it and asked

what they think about it.

MS. SMITH: Okay. Thank you.

MR. VAN DUYN: Talking about the factors in which you would develop a criterion on, we would caution against -- it just depends so much on what crop you are talking about and what product you are talking about. You can talk about the traits. You can talk about the growing regions. You can talk about the crop, nontarget organisms in the area, the presence of water versus not having water, an arid region versus a more temperate region; and if the product has ever been introduced into the region. If they are naturally occurring cousins of the plants, such as the naturally occurring cotton rise in Southern Florida or in Arizona.

So there are so many different factors, we would caution against having any sort of -- and I'm not suggesting that it would be, but an arbitrary process by which something is more from familiar and, therefore, can be deemed safe. Because when you introduce a new crop, you are introducing a whole different set of variables into the equation, some of which will make it a lot lower risk and some of which will make it a lot higher risk. So we would encourage USDA to take those into consideration.

Also, we would like to point out that novel technologies should not be included into a familiar situation because, of course, they are novel and they can't be familiar. So those will be something that will have to be continued to be regulated very stringently.

Moving on to the next question you have, No. 3: Whereas, this is considering ways to provide regulatory flexibility for future decisions by allowing for commercialization of certain genetically engineered organisms while continuing, in some cases, to regulate the organisms based on minor unresolved risks.

Based on past experience such as the Starlink episode, we don't feel that this is a particularly good idea. The test should be risk based, and minimal risks shouldn't be tested. So the system should be on a risk basis.

If the USDA determines that the risk is insignificant, then there's really no reason to run a test. So you wouldn't have a minimal-unresolved risk versus major risks that are done. So I don't see where this is constructive. If I'm missing the point on the purpose of this thought, then I would ask that you please educate me.

MS. SMITH: No, the idea is just that there may be some products that come through where there is a minor risk that perhaps a longer period of time that is available would be required to gather additional data, even though it looks like something that is going to be of a minor risk, but it's something that we still want to have the --

(Intercom interruption.)

MR. DUYN: Am I invited for cookies?

MS. SMITH: If there's any left by the time we get finished talking. Those things usually go quick, especially when they announce there's food available.

Again, the idea is if there is something, for example, a situation where the science suggests that there's a minor unresolved risk that perhaps it's something that you might need five years to gather the data, what we want to be able to do is balance the risk with the advancement of that technology. If it's a minor risk, we still want to gather that much information. We want to leave ourselves some flexibility.

I don't know, John, if you have a specific example.

MR. TURNER: We talked about several things,

but I am hesitant to give an example because it would be done on a case-by-case basis. But any monitoring would be tied to a scientific risk. It wouldn't be monitoring for monitoring. The vast majority of the products would likely go through just as they do now and be deregulated without any monitoring requirements. There might be some rare situations where we thought the risks could be managed but that we would allow it to go into a commercial-type situation.

MS. SMITH: One of the things we're trying to do here is because as the coordinated framework was first envisioned, as insightful and long standing as that was, at that point, the pharmaceuticals and industrials being incorporated, crop plants wasn't envisioned. So what we are asking ourselves now is: What are we likely to see on the horizon that we're not familiar with now, and are there ways we can build flexibility into the regulatory system to be able to help better position us for the yet unknown? So that's kind of what we're trying to get at with that piece of flexibility.

MR. VAN DUYN: Flexibility is certainly a good thing, and we are all in favor of being able to adapt to new technologies that come down the road.

This is such an advanced and constantly evolving science that new technologies are found on a relatively regular basis. Whether or not they're ready for commercialization or not, ideas are certainly spinning quicker than anyone can keep up with.

So as far as the principle of flexibility, we are in support of that, but we want to be careful about giving the impression that the regulatory system has gaps or holes in which something can slip through, as I'm sure anyone who reads the paper can pick up on pretty much anything that will go wrong will end up on the front page of some paper somewhere. That kind of bad press leads to the obvious results of people's fears and paranoia about technologies that they don't understand. So when the only information out is bad information or negative press on that particular technology, then you have a harder time getting people to invest and adapt to those types of technologies, so that's the concern with that.

MS. SMITH: Thank you.

MR. VAN DUYN: Just from my understanding right now, that's our position, but I'm sure there are certain circumstances which will merit them. Moving on to the fourth question, regarding should the review

process, permit conditions and other requirements for nonfood crops used for production of pharmaceutical and industrial compounds differ from those in food crops?

All that I can say about that, because of my limited knowledge of the industrial and pharmaceutical compounds, most of those compounds, or at least all of them I know of are either in tobacco and corn and potatoes, I think, but regardless, not in cotton -- that we would ask that they be very stringently regulated for obvious reasons. As someone told me a couple days ago, we don't want your food in our drugs, just like you don't want our drugs in your corn flakes. So I think that for the same reason as just mentioned it would be very negative if someone found some sort of pharmaceutical product in their corn flakes.

Moving on to the fifth question for noxious weeds. As defined in the PPA, this includes not only plants but also plant products. Based on that authority, APHIS is considering a regulation of nonviable plant material. We are a bit confused by this and wondering what the point of regulating nonviable plant material is, since the major concern is gene flow. So nonviable plant material, by

definition, they can't spread the genes and therefore not be introduced into the environment, so we were wondering what the point of this thought was.

MS. SMITH: It's just additional authority with the plant protection. With the noxious-weed authority, we would have the ability to do that, by the way that the definition of the noxious-weed authority is. We've not come to any strong conclusions one way or the other. But in terms of transparency and an open dialogue with the public, we want to make sure that the public is aware that this is one avenue that is available to us and is something that we would appreciate hearing input upon, whether that's something that any stakeholder groups or the public see value in our exercising that authority.

MR. VAN DUYN: Well, based on the current way that the plants are deregulated in the system: a plant is deemed to be either equivalent to a normal cotton plant that's out there or it's not. So if something is deregulated, then there would be no need to regulate nonviable plant material because it's just like any other cotton plant out there.

MR. TURNER: In that case, it certainly wouldn't be. This would be in the field-testing stage when it's still regulated.

MR. VAN DUYN: Okay. So --

MR. TURNER: Here again, under permit conditions, we say how a field test has to be terminated. It gives us a little bit of ability to follow through on that, even after the plant is tested.

MR. VAN DUYN: So the point of this would be, I guess, monitoring volunteers for next year would not be nonviable. But when a cotton crop is mowed down, you still have the stems and the roots. So if you are talking a pharmaceutical compound, then you would want that product to be dished (ph) or burned or some other method of disposal for the obvious reasons of not introducing into animal life or whatnot. Is that what you are getting at?

MR. TURNER: That's one of the considerations there.

MR. VAN DUYN: Okay. Moving on to the sixth question. APHIS is considering establishing a new mechanism involving APHIS, the state's producer for commercial production of plants not intended for food and feed, where the producer would prefer to develop and extract pharmaceutical and industrial compounds under confinement conditions with government oversight, rather than use the approval process for

unconfined releases.

This again, the point being directed toward pharmaceutical and industrial compounds is where I'm taking it. We believe that if it is hazardous or there is perceived to be a large risk prior to deregulation, or even in lieu of deregulation, that it should be much more stringently regulated or monitored by government oversight than would be a conventional or more understood technology that has been deregulated and is determined to be no different than any other plant.

Is there any feedback that you would like to give as to what scenarios that you were envisioning on this, or how a farmer can decide that they would want to raise a crop like this without deregulation or not under any of the permit conditions?

MS. SMITH: Sure. I could share a little something about what we're considering here. That is that currently, crops have the ability if they meet certain safety criteria to apply for deregulation. So if they meet that safety criteria, then that trait and that crop can become deregulated or approved.

What we are looking at is for pharmaceuticals and industrials, one of the things that we have heard is that there's a lot of interest

in maintaining those under regulation, rather than exercising the option that if they meet all the safety criteria -- if you had a pharmaceutical, let's say, growing into a crop plant that was perfectly safe to be consumed, for example, providing another option besides the option of meeting all those safety criteria to potentially be deregulated, then that option would be something where that trait in that crop could be produced so that that is taken to commercialization while still under government oversight.

So what we're envisioning there is trying to establish some kind of an additional mechanism that we don't have in the system now, so that if you wanted to manufacture something in cotton that was a pharmaceutical but you wanted to maintain that under a government oversight, there would be a better mechanism to do that in a way that would be more efficient for you, more efficient for us, and be more transparent to the public.

For example, one of the issues that we hear raised by the public now is that they need more transparency, more information about pharmaceuticals and industrials that are being brought for commercialization purposes. Right now, there are

limitations due to confidential business information and how transparent we can be in terms of what's actually out there being field tested. So what we're looking at, in terms of establishing a new mechanism, is something that might have an aspect to it that would allow more transparency.

So while you might have something that, because of your confidential business information made you wouldn't want to provide real specific information, you could put together some information that would at least help the public understand more generally what it is that's being grown in that cotton plant, as well as what the safeguards are that are put in place to ensure confinement of that.

Another aspect of this is for pharmaceuticals and industrials, we expect to be going to commercialization. You are probably going to have a situation where you are going to do the same field test for a number of years to extract whatever that is you're growing in that plant. Rather than apply for a brand new permit every year and you put together a brand new package of information and you're asked to do a full review every year, what we want to look at is a mechanism that factors in that long time commitment that there's going to be for that growth

and consider some way to have a package of information that's updated and that our evaluation of that situation may be -- we do a lot of evaluation at the beginning of the process, and then, as new information is learned, we require new information that establishes the results of each year's conduct of that field test. Then that new information is provided to us, and we're doing an evaluation on that newer information rather than starting over.

So what we're looking at here is essentially an additional mechanism that would be tailor-made for the situation, when we are expecting pharmaceuticals and industrials to be grown with any crop plants and still maintained under regulation.

MR. VAN DUYN: We would encourage APHIS, if that was an avenue that was to be taken, to have designations for where those type of plants and compounds lie within the regulatory system, as opposed to having -- right now, you have two status. One is deregulated; the other is not deregulated. Not deregulated could mean several places within the system.

If you are planning on doing something like that, then there should be some sort of designation whether or not it would be permanently not

deregulated, so that you're classified as a government-controlled compound; or, in the permit condition, to where you are in an experimentally use-permit situation, so it's being tested for deregulation. There needs to be some sort of designation for where that compound sits within the regulatory structure for the purposes of understanding and transparency. Because if it's in deregulation, it could mean any one of several things.

So I think that would be particularly helpful in transparency and also allow the registrants, and the growers know where they stand with the government as far as compliance.

MS. SMITH: Good point. Thank you.

MR. VAN DUYN: Additionally, when determining those types of things -- and I'm sure that you're aware and have probably even looked into it -- the FDA has good clinical practices and good manufacturing practices, some in the biopharming, "pharming" with a "PH," industry have said that their farming operations should be regulated under good manufacturing processes, just like their manufacturing processes in the steel container when they extract the compound and turn it into the final bill.

So I would encourage taking tidbits or

whatever information is gleaned from those practices and applying it as well for proper control and documentation of where those products are.

Moving on to the seventh one, the current regulations and the provisions for adventitious presence and should APHIS establish a separate component within a revised regulatory system to address adventitious presence?

The only question that we had was: How was this different from the current threshold levels?

MS. SMITH: We don't currently have threshold levels for something that's not been through the regulatory system. What we're talking about here with adventitious presence is determining if there will be times in which the low and intermittent occurrence of something that's not cleared all of the regulatory hurdles, whether there will be times in which low and intermittent levels of that will be exempted from -- if their occurrence happens, whether it's exempted from a violation of our regulations.

What we envision here is, as we are looking at a multitiered risk-based system, there may be a level in which there is no risk associated with, for certain organisms, some intermittent and low-level occurrence of these genetically engineered traits. If

they can meet certain safety criteria, then we would consider exempting them if they occurred at a low and intermittent level.

MR. VAN DUYN: Okay. Of course, something that's not been deregulated and is in *de minimis* amounts -- in a grain shipment, the shipment would be considered an adulterated food under FFDCA. That would be highly conditional, depending on what the product is. Getting back to the food-safety assessment that you were talking about, that would be something that would be critical in making one of those determinations, which, by the way, we think is a good idea, is doing the food-safety determination -- someone should in every regulatory decision made on a Biotech plant.

So regardless of whether or not it's going to have *de minimis* levels of acceptance or not -- but yes, just having some sort of threshold standard -- the European Union currently for Biotech products is at .9. Some go as high as five percent. A certified seed in the United States is regulated at 98 percent.

So if you have a *de minimis* acceptance at .9 in the case of the European Union, then you never become within compliance because you were only certified under the 98 percent, so you have to label

as, you know, this may have something we don't know in it. It may have a *de minimis* amount.

So I would advise that you review the current standards for things such as certified seed in current agricultural programs and take that into consideration if you're going to establish thresholds or establish tolerances or anything of that nature in making those decisions.

MS. SMITH: It's probably worth noting that our natural inclination is not toward tolerance levels, because we consider it our responsibility to ensure confinement. The way we are currently thinking about approaching this is on very much of a case-by-case basis; and looking at each of those cases to the extent to which they might meet some preestablished criteria.

MR. VAN DUYN: What would be the preestablished criteria that you have in mind for this? Because if you say it's going you are going to have to preestablish criteria, but everything is going to be case-by-case, then you are running into a possible conflict.

MS. SMITH: Right. Now, the preestablished criteria would have to do with safety essentially, so it would have to be safe to eat, that kind of thing.

MR. VAN DUYN: Okay. Moving on to No. 8: Should APHIS provide for expedited review, or exemption from review, of certain low-risk genetically engineered commodities intended for importation that have received all necessary regulatory approvals in their country of origin and are not intended for propagation in the United States?

I think that the United States has the most advanced regulatory system in the world, and that if the United States' regulatory system believes that it is a safe product, that it will be sold. I think that maintaining guidelines for food products and those not intended for food for commodities, regardless of their country of origin, should be applicable.

There's no comment on that?

MR. TURNER: Look, one situation people presented us with more shipments that would be coming here. Perhaps they've been through FDA, the Biotech shipments but there are no food-safety issues, but they haven't through a review. What do you do with those, if it's not intended for propagation? So that's sort of the idea.

MR. VAN DUYN: Are you talking about seed for planting?

MR. TURNER: No, commodities.

MR. VAN DUYN: Commodities for consumption?

MR. TURNER: Right. So it shouldn't go into the ground. It's cleared for food use. Would it need to go through the USDA?

MR. VAN DUYN: Maybe not USDA. It would depend on what the commodity is and what you're looking for. If you are talking about the EPA and it has a substance that's currently banned by the International PPS Treaty, then any presence of those materials would be considered an adulterated compound under FEDCA. So there are other considerations of pesticides or what have you, if it's a plant-incorporated protectant, which the EPA hasn't authorized, then that would be a consideration.

So there are other factors and so it should go through some sort of regulatory review, maybe not APHIS or USDA. But it needs to go through the same regulatory approvals that the United States does, because otherwise you are setting up a competitive disadvantage where someone has to regulate a particular type of herbicide, fungicide or Biotech product.

If it doesn't have to be looked at as closely because it's imported, then you're giving foreign countries a competitive advantage on their

importations of food shipments, which is a cost of doing business that the United States bears a lot and a lot of other countries do not, because they don't have regulatory systems or some of the more advanced technologies we have, so they rely on older technologies which we may have banned.

MS. SMITH: Good comment.

MR. VAN DUYN: Moving on to No. 9, currently, genetically engineered or Arabidopsis. Should the regulation of other similar genetically engineered plants be consistent with the regulation of genetically engineered Arabidopsis? Should the exemption from interstate movement restrictions apply only to those products that meet specific risk-based criteria? We believe that it should be exempted only if completely deregulated. Otherwise, it should be regulated.

Deregulation implies that it's no different than any other plant, but if it's continually regulated, then you are designating it being the same as, or not the same as, a non-Biotech counterpart. So it should be subject to the same regulations because a deregulated plant will have gone to the risk analyses and be determined to have been safe to the environment, even health. And one that is currently

regulated, there is still questions that need to be answered. While those questions are out there, then the regulatory process should be cautious.

MR. TURNER: Even for lab-to-lab interstate movement? That's sort of the question.

MR. VAN DUYN: The lab-to-lab interstate movement may not be the same as a bulk-commodity shipment from state to state, but there should certainly be protocols on how those products are handed. Arabidopsis may have a particular type of gene in it which may be compatible with a native species.

In a lab situation, you're dealing with more cutting-edge technologies which have less known about them. So the plant itself may not be a particular problem, but the trait which it carries may be a problem.

Now, of course, this again is conditional, because that particular type of plant may not have any native species in which it is compatible with and absolutely no way that you could possibly have gene flow. But those are situations that need to be determined and need to be looked at, as opposed to taking up a particular type of plant and saying: Well, it's a pine tree or it's a what have you, based on

what is known and then making assumptions.

The whole burden of what process means needs to be executed. I suppose it's possible for something like that to be exempted in a lab-to-lab situation or even in a bulk situation, but I foresee that those type of situations will be few and far between.

We had no questions about No. 10, had no further comments on No. 10 about other areas that should be regulated. No. 11: What environmental considerations should be evaluated if APHIS were to move from prescriptive-container requirements for shipment of genetically engineered organisms to performance-based container requirements?

We believe that there should be certain standards for container shipments. If something is in excess of a USDA-certified and bioengineered-plant containment system, then that should be something that should be a business decision for the particular shipping company, as long as it meets the minimum requirements of the regulatory agency.

Based on the EIS that was released in the Federal Register, those are all the comments we have for now.

MS. SMITH: Okay.

MR. VAN DUYN: We look forward to seeing the

future regulation and how this develops within the Agency. We will be happy to participate. If you have any questions or other things that you are considering, I would be happy to entertain some questions.

MS. SMITH: Great. Well, thank you. We appreciate your time and your comments. I think we do have a couple of questions.

Robyn, did you have a question?

MS. ROSE: I am not sure if it is an appropriate question.

MS. SMITH: I think you can ask the question.

MS. ROSE: Okay.

MS. SMITH: Come up to this mike right here.

MS. ROSE: I am Robyn Rose with QRS, and I particularly asked this question because you introduced yourself as being the coordinator of the environmental aspects of Biotech for the National Cotton Council. My question is related to monitoring for ecological effects. Where do you think the Cotton Council sees APHIS's role is for monitoring for potential environmental effects, like affects the nontarget populations or insect-resistance management, and where is APHIS's role in relation to EPA's role,

or versus EPA's role in that?

MR. VAN DUYN: I think that the regulatory roles are fairly well spelled out in the guidelines which allow them to make the regulations in the first place, the Plant Protection Act and FIFRA, in which the EPA monitors insecticidal compounds. So when you're talking about BT compounds, then it would be more in their domain to talk about insect-resistance management, because you're talking about a pesticide risk with insects rather than a potential noxious-weed risk that APHIS would oversee.

MS. ROSE: And that includes not just stating what the regulations are but that monitoring to make sure that these effects are not occurring, I think is under this.

MR. VAN DUYN: The monitoring should take place in the risk-evaluation process. The BT technologies that are currently out in cotton, part of that registration process they needed to go through was they needed to fill up the requisite requirements. Part of those requisite requirements was -- in cotton, it's an 80/20 or 95/5, either in trained five percent or external five percent, which is not sprayed. Those kind of things are part of the registration process.

Before receiving full registration for the

commercialization of that product, those particular risks were hashed out and addressed. I think that should be part of the regulatory process.

MS. SMITH: Good question.

MS. BECH: To get back to Question 8 where we talked about the approval process; and, in particular, there was the discussion about commodities coming in. My question would be for a commodity coming in for processing, not for food or feed, and not to be grown here, propagated, the regulatory system that we have ensures environmental safety because it's being grown or food safety as being consumed.

But if you have a product like cotton linters that would be coming in from, say, somewhere where they developed a genetically engineered crop and they're bringing the linters in, do you still feel that they should undergo the same regulatory process, or there would be a different process for that, because it won't be grown here and it won't be consumed?

MR. VAN DUYN: First off, I would just like to say that I don't foresee us importing cotton linters for processing because we like to buy our own. But in the event that it were to happen, it would be

conditional. Cotton linters, the cotton fiber is pure cellulose, both Biotech and non-Biotech, so it does not contain any DNA fragments. As a matter of fact, it doesn't contain any sort of protein. It's just pure cellulose.

So that would be a situation in which the product would be reviewed. You would say this commodity has no potential to have a gene flow or whatnot. That wouldn't exempt it from any sort of EPA review for whatever chemicals were placed on it or what have you. But as far as the Biotech component of it, the linter itself would not be subject to a particular review because it has no DNA and it has no presence of the protein in it.

If you are referring to a kernel of corn that's going to be pressed into oil, if it's pressed into oil and the oil is shipped here, then again the oil is processed in such a way in which it contains no DNA and no protein. If you tested the oils, to my knowledge, there's no way of determining whether or not it's Biotech or not. But the kernel, which has a living modified organism in it, is a different story.

So if it is a novel trait which is not used in the United States, then it would be subject to the same regulatory responsibilities that all the other

products are because there is potential for it being introduced into the environment.

MS. SMITH: Do we have other questions?

Okay, well, we really appreciate you coming in and appreciate your time and look forward to being able to factor your input into our decisionmaking. We look forward to your written comments and continuing this file.

MR. VAN DUYN: Thank you very much.

MS. SMITH: Thanks a lot. If I could ask the staff to stay at the conclusion of the meeting.

(Whereupon, at 2:30 p.m., the meeting was concluded.)

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REPORTER'S CERTIFICATE

TITLE: Stakeholders Meetings
(National Cotton Council of America)

HEARING DATE: February 23, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 23, 2004

Renee Miskell

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